

Attorney Docket No. E3691-00102

REMARKS

This Amendment and the concurrently filed Request for Continued Examination are filed with a Five Month Extension of Time. This extends the deadline to submit a timely response or take appropriate action in connection with the Notice of Appeal filed August 18, 2009 until March 18, 2010.

The Final Office Action mailed February 18, 2009 rejected claims 129-161. Claims 162 to 171 were withdrawn by the Examiner from consideration as directed to a non-elected invention.

Claim 146 has been amended. Claims 160 and 161 have been cancelled without prejudice. Claims 162 to 171 which have been withdrawn from consideration as directed to a non-elected invention. Although applicants disagree with the Examiner's position, Applicants have cancelled these claims in order to expedite prosecution and allowance of this application. Applicants reserve their rights to file divisional applications and/or continuation applications directed to the subject matter of the cancelled claims and/or to any non-elected invention.

THE SECTION 112 NEW MATTER REJECTIONS.

Claims 146 to 161 were rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. The Examiner has asserted that claims 146 to 161 lack support for the limitation "wherein triethylenetetramine and succinic acid are purified."

Although Applicants disagree with the Examiner's assertion, they have amended claim 146. Claim 146, as presently amended, specifies that the acid addition salt is prepared using an acid which yields a physiologically acceptable salt. Applicants submit that this language is clearly supported by the specification. See, e.g. page 30, first full paragraph of published PCT application WO2004/017956 (upon which this U.S. National phase application is based). This also corresponds to paragraph 0130 at page 13 of the corresponding published U.S. application US 2006/0100278.

Claims 147 to 159 and now cancelled claim 160 and 161 were dependent or ultimately

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dependent on claim 146.

Applicants submit that claim 146 as presently pending and those claims which depend from it (as Claims 147 to 159 and 172 to 175) as amended gives rise to no issue of new matter.

THE SECTION 112 WRITTEN DESCRIPTION REJECTIONS

Claims 160 and 161 stand rejected under 35 U.S.C. §112, first paragraph as assertedly containing subject matter not complying with written description. In particular, the Examiner appears to object to “delivery agent” and “reverse active transport agent” in those claims.

Applicants submit that the Examiner’s position is not well taken and those terms, when considered within the description set forth at pages 73 to 77 of the published PCT application (paragraphs 0241 to 0250 of US 2006/0100278), are clearly compliant with the first paragraph of Section 112. However, in order to expedite reconsideration of their invention as claimed, claims 160 and 161 have been cancelled without prejudice. New claims 172 to 175 have been added. These claims are clearly described in the specification as noted above.

**THE SECTION 112, FIRST PARAGRAPH, REJECTION
(WRITTEN DESCRIPTION) AT PAGE 3**

Claims 160 and 161 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly not complying with the written description requirement. Applicants submit that the Examiner’s position is not well taken and traverse this rejection.

The Examiner appears to object to the terms “delivery agent” and “reverse active transport agent”.

Applicants note that the application provides ample description and exemplification of “delivery agent” and “reverse active transport agent”. See, e.g. pages 73 to 77 of the Application.

Moreover, Applicants submit that agents useful for use as a “delivery agent” and/or a “reverse active transport agent” would be known to one of skill in the pharmaceutical formulation arts.

Accordingly, applicants submit that claims 160 and 161 clearly comply with the first paragraph of Section 112. Applicants request that the Examiner reconsider this rejection and withdraw it.

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THE SECTION 103 REJECTION

Claims 129 to 161 were rejected under 35 U.S.C. § 103 as unpatentable over published United States Patent Application US 2003/0055113.

This rejection is traversed. Wang et al neither suggest nor make obvious the subject matter of claims 129 to 159 and 172 to 175.

As they noted in their previous response, Applicants are investigating whether Wang et al constitute properly citable prior art against the present application. Applicants' traverse of the rejection over Wang et al is not an acknowledgement that Wang et al constitutes properly citable prior art.

Even should Wang et al constitute properly citable prior art under either 35 U.S.C. §§ 102 and 103, applicants submit that Wang et al neither suggest nor make obvious the subject matter of claims 129 to 161.

Wang et al are concerned with methods for treating ocular inflammation, particularly inflammation secondary to laser therapy of choroidal neovascularization. (See, e.g. Wang [0006]). Wang et al are also concerned with pharmaceutical compositions adapted to ocular administration and which use "an ophthalmologically acceptable carrier". The Examiner admits at page 6 in The Office Action mailed May 28, 2008 that Wang et al do not teach that "[t]he specific salt is formed from succinic acid" (page 6) and "the Examiner acknowledges that 'picking and choosing' within several variables does not necessarily give rise to anticipation" (page 7). The Examiner further admits "where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found" (page 7).

Applicants note that the Examiner's apparent original justification for the present rejection (citing KSR v. Teleflex 127 S.Ct 1727, 1741(2007)) was as follows:

The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Idm at 1742. Consistent with this reasoning, it would have obvious to have selected succinic acid from the list of organic acids disclosed by the prior art to form a salt of triethylenetetramine, to arrive at compositions "yielding no more than one would expect from such an arrangement".

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May 28, 2008 Office Action, page 7.

Applicants note that the Examiner fails to provide any rationale to select succinic acid from a list of acids set forth in Wang. In particular, paragraph [0046] cited by the Examiner, broadly includes "inorganic acids" and "organic Acids" and would include a large number of possibilities. It is established and, indeed even exemplified in the USPTO's own materials that "Examiners must articulate findings of fact to support the obviousness rejection being made." Applicants submit that no such findings were set forth in the present obviousness rejection. Merely asserting it would be "obvious" without giving any reason, rationale or motivation does not suffice to render it so.

In view of the different contemplated uses of Wang et al for their ophthalmic compositions and, when considered in the context of what Wang et al would fairly teach or make obvious to one of skill in the art, the present rejection over Wang et al should not stand. Applicants request that the Examiner reconsider the present rejection and withdraw it.

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CONCLUSION

Applicants submit that, in view of the foregoing, Claims 146 to 159 and 172 to 175 are allowable. Applicants request that the claims be allowed and passed to issue.

Should any issues or questions remain, or if the Examiner believes that a telephone interview would expedite prosecution and allowance of this application, the Examiner is encouraged to telephone the undersigned applicants' attorney at (619) 744.2210.

Commissioner is hereby authorized to charge any requisite fees for this submission, or any fees in connection with this application during its entire pendency, or to credit any overpayment, to Deposit Account No. 04-1679.

Dated: March 18, 2010

Respectfully submitted.

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